RESPIN 11 USER MANUAL (CEI EN 62079)

READ ALL INSTRUCTIONS BEFORE USING

Warnings about the use of this booklet:

- The User Manual is part of the product
- It is important to keep the User Manual during the entire life cycle of the product
- The User Manual must be transferred to any subsequent owner or user of the product

RespIn 11 Bronchial Clearance System

The information contained in this manual is subject to change without notice.

No part of this text shall be reproduced in any form without written permission from RespInnovation SAS.

The latest version of the User Manual can always be found on our site at www.respinnovation.com.

Version 4.1 – 23092013

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INTRODUCTION

This manual includes instructions for setup, use and maintenance of your RespIn 11 Bronchial Clearance System. It is to be used as a reference guide. Please review all the sections carefully before you use the system.

Caution: US Federal law restricts this device to sale by or on the order of a physician.

1. - IDENTIFICATION

1.1. - PRODUCT BRAND AND TYPE DEFINITION

PRODUCT NAME: RespIn 11

MANUFACTURER: RespInnovation SAS

1.2. - PRODUCT VERSION

SERIAL NUMBER:

CE MARK: CE 0434

LOCATION OF THE ID: on the rear panel of the RespIn 11 device.

1.3. - MANUFACTURER, SUPPLIER, DISTRIBUTOR NAME AND ADDRESS

MANUFACTURER NAME: RespInnovation SAS

MANUFACTURER ADDRESS: 611, chemin de l'Adrech - 83440 SEILLANS, France

TELEPHONE NUMBER: +33 4 94 76 58 45

WEBSITE: www.respinnovation.com

E-MAIL: info@respinnovation.com

Only Distributors can sell the RespIn 11 Bronchial Clearance Device. Do not re-sell RespIn 11 Bronchial Clearance Device to third parties before and without communicating this to your RespInnovation approved sellers/distributors.

RespInnovation SAS reserves the right to make changes without notice in design, specifications, and models.

1.4. - DECLARATION OF CONFORMITY

RespInnovation SAS
611, chemin de l'adrech – 83440 Seillans (FRANCE) • P.I. FR87528273568
Tel. +33.489719568 • info@respinnovation.com • www.respinnovation.com

Declaration of Conformity

Seillans, xx/xx/xxxx

RespInnovation SAS declares that the Bronchial Clearance Device of Class IIa:

SAMPLE

RespIn11
Model RI110000
SN AA01xxxx

complies with the MDD 93/42/EEC and subsequent amendments and additions. It was assessed by the Certification Body CE_{0434} *Det Norske Veritas Certification AS, Norway* according to Annex II, excluding Section 4 of MDD 93/42/EEC and subsequent amendments and additions.

Barrett Mitchell

_____
Legal Representative

Branch Office Italia:
via IV novembre, 33 • 00040 Albano Laziale (RM) • Tel. 06.9322854

Declaration of Conformity – 07/05/2012 rev. 1

2. - PRODUCT SPECIFICATION

2.1. - GENERAL FEATURES, APPLICATIONS AND INTENDED USE

USER'S DESCRIPTION

The device can be used autonomously by the patient (for adults only), requiring only 2 or 3 simple instructions. Furthermore, the device requires no installation or planned maintenance. There are no special environmental characteristics for the premises where it is to be used beyond the minimum requirements for domestic premises. In case of failure, RespInnovation SAS or RespInnovation SAS's appointed dealer must be immediately advised and a replacement unit will be dispatched. The faulty equipment must then be returned to your supplier or directly to RespInnovation SAS for repair by their technicians or other technicians specifically trained and authorized by RespInnovation SAS.

INDICATIONS FOR USE

The RespIn 11 is intended to provide bronchial clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy' (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the RespIn 11 is also indicated for external manipulation of the thorax to promote bronchial clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

The use of RespIn 11 is indicated for treatment of bronchial obstruction (airway lumen reduction with secretions stasis and possible bacterial over-infection). This alteration is characterized by edema, peri-bronchial muscle spasm and hyper-secretion in response to inflammatory, infectious and irritating stimuli.

The primary purpose of such therapy is to reduce or eliminate bronchial obstruction, preventing complications from stasis of secretions, improve mucociliary clearance and the effectiveness of cough.

INTENDED ENVIRONMENT OF USE

RespIn 11 is intended to be used in hospital, sub-acute, clinician offices and home environment.

KNOWN / FORESEEABLE CONTRAINDICATIONS

According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the Bronchial Clearance Device requires careful consideration and assessment of the individual patient's case if the following conditions exist:

- Intracranial pressure (ICP) greater than 20 mm Hg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Head and/or neck injury that has not yet been stabilized
- Active hemorrhage with hemodynamic instability
- Distended abdomen
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
- Subcutaneous emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Coagulopathy
- Complaint of chest wall pain
- Rib fractures, with or without flail chest (within 30 days – after this may help splint/stabilize)
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Recent esophageal surgery
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous or subcutaneous pacemaker (within 30 days)

Currently in the European market there is no medical device for delivering of HFCWO therapy, so RespInnovation SAS refers to the AARC Guidelines for the definition of Contraindications.

2.2. - DIMENSIONS AND WEIGHT

DIMENSIONS: 370mm x 230mm x 260mm

WEIGHT: 10 kg

2.3. - POWER SUPPLY INFORMATION

ELECTRICAL REQUIREMENTS: 100-240 VAC, 50-60 Hz, 4.7A MAX

FUSE: 3 Amp.

POWER SUPPLY INSULATION: Input to Ground 2.5kVAC, Input to Output 3kVAC, Output to Ground 500VAC for 1 min.

WARNING

Separable electrical connector - Do not place the medical device in a position which makes it difficult to disconnect.

2.4. - NOISE EMISSIONS

NOISE EMISSION: 63dB.

2.5. - ENVIRONMENTAL TRANSPORT / STORAGE AND WORKING CONDITIONS

ENVIRONMENTAL TRANSPORT AND STORAGE CONDITIONS:

CONDITION	RANGE
TEMPERATURE	from -20°C to 70°C
HUMIDITY (RH)	from 10% to 100%
ATMOSPHERIC PRESSURE	from 500hPa to 1060hPa

ENVIRONMENTAL WORKING CONDITIONS:

CONDITION	RANGE
TEMPERATURE	from 0°C to 40°C
HUMIDITY (RH)	from 10% to 100%
ATMOSPHERIC PRESSURE	from 500hPa to 1060hPa

2.6. - SAFETY RELATED INFORMATION

QUALITY AND TECHNICAL ASSURANCE	CEI EN 60601-1
DEVICE CLASSIFICATION (EN 60601-1)	EXTERNAL POWER SUPPLY: CLASS I
APPLIED PARTS (PROTECTION LEVEL AGAINST ELECTRIC SHOCK)	B WITH F APPLIED PART
CLASSIFICATION ACCORDING TO MDD 93/42/EEC	IIa
CHASSIS (PROTECTION AGAINST THE WATER/DUST ENTRY ACCORDING TO IEC 60529 - TAB. D.3)	IP20
STERILIZATION METHOD	NOT APPLICABLE
USE IN OXYGEN RICH ENVIRONMENT	NOT PROVIDED
MODE	INTERMITTENT: maximum time duration of activation (ON): 30 min minimum time of deactivation (OFF): 5 min

3. - PRODUCT SYMBOLS

Dangerous voltage within the device may constitute a risk of electrical shock.

IP20 — Not protected against water ingress.

Earth/Ground

Type BF equipment with an F-type applied part, according to EN 60601-1.

Operating Instructions.

Manufacturer

Year of Production

4. - WARNINGS & SAFETY WARNINGS

UNSUITABLE FOR CHILDREN
NOT SUITABLE FOR USE IN BATHROOM OR DAMP AREAS
INDOOR USE ONLY

Rx ONLY

ELECTRICAL SHOCK HAZARD WARNING

SITTING ON DEVICE PROHIBITED

STEPPING ON DEVICE PROHIBITED

5. - PREPARATION FOR USE

5.1. - SAFETY WARNINGS PRIOR TO USING

To reduce the risk of burns, electric shock, fire, or personal injury, follow these instructions. Failure to do so could cause personal injury or equipment damage.

Always unplug this product immediately after using.

Patients that may have difficulty clearing secretions from the upper airway (such as those with Motor Neuron Disease (MND) or other advanced neuromuscular or neurological disorders) may require specialized therapy programs Involving manually or mechanically assisted coughing or other techniques in conjunction with RespIn 11 Bronchial Clearance Device therapy. Please consult your physician to determine if additional therapy is appropriate.

Close supervision throughout the treatment is necessary when this product is used by children or patients with physical limitations or impaired cognitive abilities.

Use this product only for its intended use as described in this manual.

If this product has a damaged Power Cord or plug, is not working properly, or has been dropped or damaged, do not operate it. For examination and repair, contact RespInnovation Service or its official local Distributors.

Keep the unit and its Power Cord away from heated surfaces.

Never drop or insert any inappropriate object into any opening on the unit.

Read and follow all instructions for setup, use, and maintenance. Failure to do so could cause patient injury or equipment damage.

Only authorized personnel should service RespIn 11 Device. Servicing by unauthorized personnel could cause personal injury or equipment damage and will invalidate any Warranty.

Any change of internal parts or spare parts not authorized from RespInnovation SAS or its Distributors may cause personal injury or equipment damage. In this case, the RespIn 11 device would no longer be considered as complying to 93/42 MDD.

The potential for electrical shock exists with electrical equipment. Failure to follow protocols may cause death or serious personal injury.

If the Device is wet or damp, do not plug it into a power source or use it. Patient injury, personal injury, or equipment damage could occur.

Use only correctly grounded electrical outlets. Failure to do so could cause equipment damage.

Before cleaning, unplug the unit from its power source. Failure to do so could cause personal injury or equipment damage.

Do not expose the unit to excessive moisture or immerse it in water. Personal injury or equipment damage could occur.

Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

Retain the original packaging material.

Do not eat or drink during a therapy session. To do so could cause a risk of choking.

5.2. - UNPACKING - LIST OF CONTENTS

1 x User Manual
1 x RespIn 11 Control Unit
1 x RespIn 11 Jacket
2 x Connection Hoses
1 x Power Supply Cord
1 x Carrying Case

5.3. - PREPARATORY WORK BEFORE INSTALLATION

Installation is not required.

5.4. - RE-PACKAGING TO PREVENT DAMAGE DURING TRANSPORT

Disconnect from RespIn 11 device and rewind hoses and power supply cord.

Retain the original packaging material. If shipping is required, the original packing material provides the best protection for the RespIn 11 device.

Place the RespIn 11 device and its accessories in the original packing taking care to protect the LCD Touch Screen from impacts.

6. - OPERATING INSTRUCTIONS

6.1. - INITIAL SETUP PROCEDURE

1 - CONNECT THE RESPIN 11 UNIT TO THE MAINS SUPPLY.

- Ensure the unit and power cord are not wet or damp.
- Plug the power cord into the rear of the unit.
- ONLY connect the unit to a grounded electrical outlet.

NOTE: The power cord required can change for different countries.

2 - FIT THE RESPIN 11 JACKET.

- A cotton t-shirt or similar clothing must be worn beneath the jacket.
- Do not wear the jacket in direct contact with the skin.
- For the best fit, inhale deeply and tighten the buckles until a “snug” fit.
- Ensure the jacket fits close to the body without being uncomfortably tight.

3 - CONNECT THE HOSES TO THE JACKET.

- Connect the jacket to the hoses provided.
- Fit the front jacket connector to the 2 hole hose.
- Fit the rear jacket connector to the 3 hole hose.
- Push and twist the hoses into the connectors until the notches are aligned to lock into position.

4 - CONNECT THE HOSES TO THE RESPIN 11 UNIT.

- Connect the unit to the hoses from the jacket.
- Fit the front jacket hose to the 2 hole connector (left).
- Fit the rear jacket hose to the 3 hole connector (right).
- Push and twist the hoses into the connectors until the notches are aligned to lock into position.

5 - SWITCH ON THE RESPIN 11 UNIT.

- Turn on the unit by using the switch located on the rear lower panel of the device.
- The unit will perform a self test whilst the logo is showing.

6 - CHOOSE THE DESIRED OPERATING MODE.

- The RespIn 11 Bronchial Clearance System MUST ONLY BE USED with a certified Doctor's prescription. The decision on the final therapy configuration and said therapy is the responsibility of the treating qualified Clinician / Doctor / Respiratory Therapist or Physical Therapist.

6.1.1. - PREFERRED THERAPY POSITION

For the most effective therapy it is recommended that if possible you sit in an upright position with your back tight to the rear of a chair.

NOTE: If your physician has described aerosol therapy to be used during the treatment, set up the appropriate equipment.

6.2. - RESPIN 11 UNIT OPERATING INSTRUCTIONS

The RespIn 11 Bronchial Clearance System MUST ONLY BE USED with a certified Doctor's prescription. The decision on the final therapy configuration and programming of said therapy for each patient for use of the RespIn 11 Bronchial Clearance System is the responsibility of the treating qualified clinician – prescribing Doctor or Respiratory Therapist or Physical Therapist.

The unauthorized use of this device without Doctor's prescription, or use of this device without professional guidance for the choice of programmed therapy is not allowed.

6.2.1. - MANUAL SETTING

- Choose "Manual Settings" touching the MANUAL button on the screen.
- Set Frequency (from 1 to 10), Power (from 1 to 10) and Time (from 5 to 30 minutes) as defined by the physician and then push the ">>" button.
- Carry out the therapy until the timer reaches the set time and the machine switches off.
- If necessary, change Frequency and Power using the "+" and "-" buttons.
- To stop/pause press the STOP button and to re-start the therapy, push the PLAY button.
- At the end of the therapy switch the device OFF and disconnect the jacket.

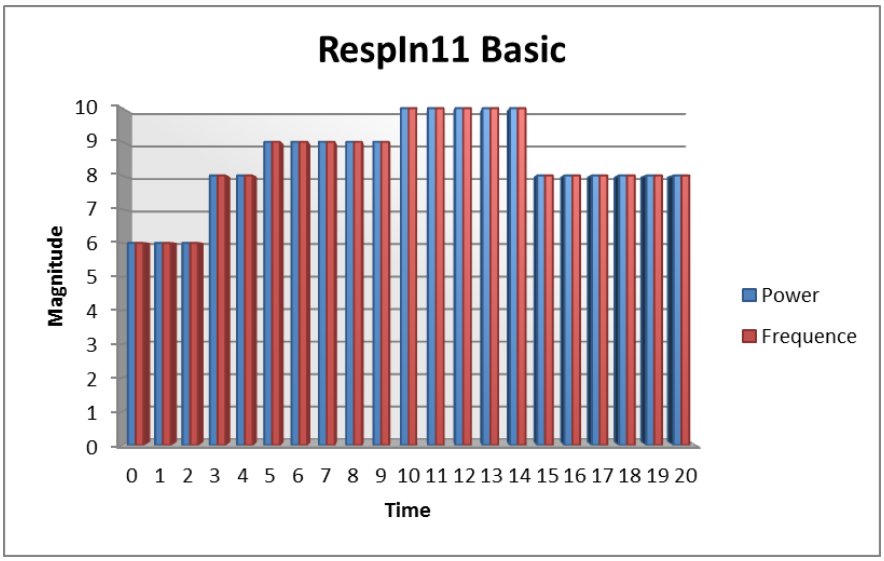
6.2.2. - PROGRAM SETTING

- In addition to the Manual Program, the prescribing Doctor or treating Clinician can choose one of the pre-loaded programs listed in "Prog Settings" below by touching the PROG button on the screen.
- Set the therapy protocol prescribed by the physician, from the following programs.

RESPIN 11 BASIC PROTOCOL

TIME: 20 minutes

FEATURE: The RespIn 11 Basic Protocol is set to pause after 10 minutes of operation. The user or the physician can take any measurements about physiological parameters of possible interest, or decide to press PLAY immediately to continue the therapy session.

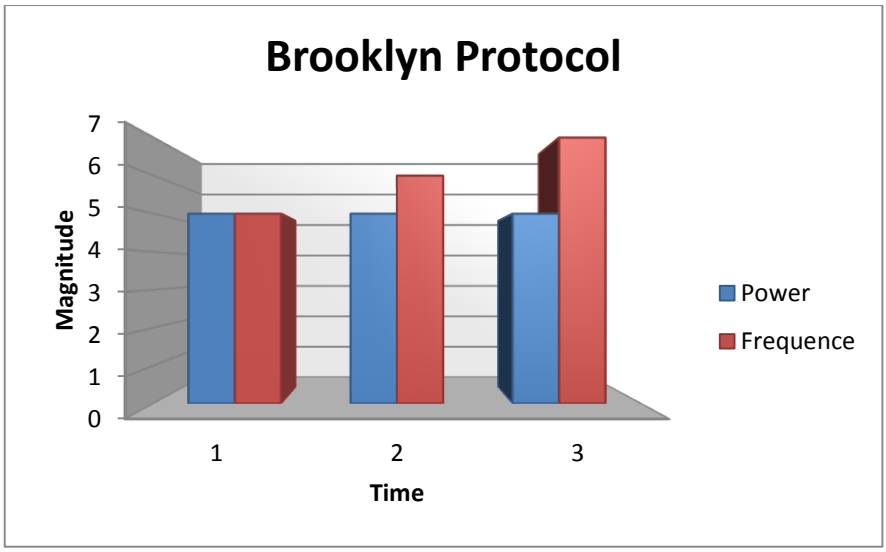


BROOKLYN PROTOCOL

TIME: to be chosen by the user or the physician (from 3 to 30 minutes)

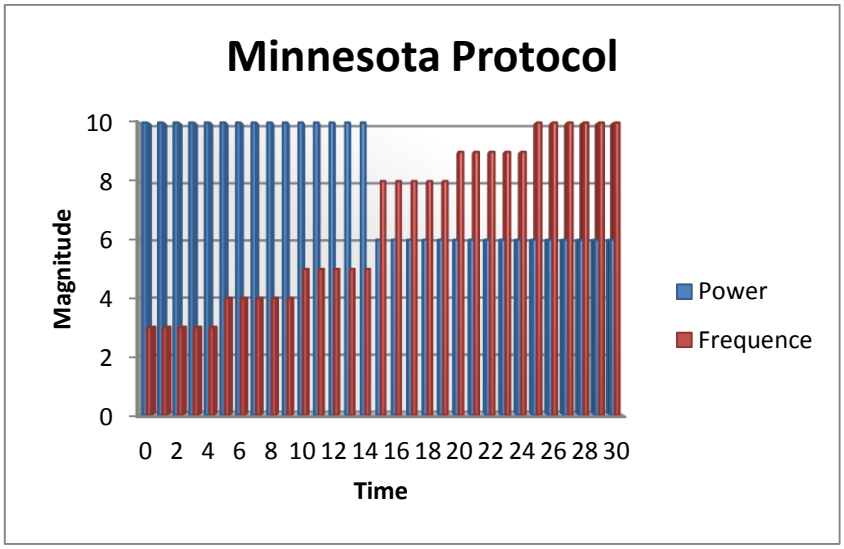
PRESSURE: to be chosen by the user or the physician (from 1 to 10) and remains constant during the therapy session.

FREQUENCY: the Brooklyn Protocol features 3 standard frequencies. Level 5 for the first third of the set time, Level 6 for the second third of the set time and Level 7 for the final third of the set time.



MINNESOTA PROTOCOL

TIME: 30 minutes



6.3. - SIGNALS TO BE OBSERVED

In case of internal failure detected by the system the following message is shown:

“ERROR FOUND – PLEASE CONTACT SERVICE”

6.4. - SWITCH OFF PROCEDURE

- Stop the running of the therapy by pressing the STOP button.
- Switch the device OFF using the ON/OFF switch located on the rear panel of the device.
- Take off the jacket.

7. - MAINTENANCE & CLEANING

The RespIn 11 Device does not require ordinary maintenance. In case of failure contact the Authorized Service (See the address at the end of this User Manual).

7.1. - SAFETY PRECAUTIONS

WARNING:

Follow the product manufacturer's instructions. Failure to do so could cause personal injury or equipment damage.

Shock Hazard:

The potential for electrical shock exists with electrical equipment. Failure to follow protocols may cause serious personal injury or death.

Unplug the unit from its power source. Failure to do so could cause personal injury or equipment damage.

Do not expose the unit to excessive moisture or put it in water or any other liquid solution. Personal injury or equipment damage could occur.

Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

7.2. - MAINTENANCE AND CLEANING BY USERS

We recommend that you wipe clean the RespIn 11 Bronchial Clearance Device and the related Jacket with surfactant detergent and warm water. Do not use excessive liquid or harsh cleansers, and do not put the device in water or any solution.

Do not use any steam cleaning device on the unit or Jacket. Excessive moisture can damage mechanisms in this unit or Jacket.

To remove difficult spots or stains, we recommend that you use standard household cleansers and a soft bristle brush. To loosen heavy, dried-on soil, you may first need to saturate the spot.

When there is visible soiling and also between patient use in multi-patient care environments, we recommend that you disinfect the unit. Use a tuberculocidal disinfectant or standard household, mild, anti-bacterial soap or solution. Dilute the disinfectant as specified on the manufacturer's label.

7.3. - DISPOSAL

The used RespIn 11 device contains valuable materials which can be reused.

Dispose of the used device in an environmentally friendly manner and in accordance with current national guidelines regarding waste disposal.

7.4. - TROUBLESHOOTING, DIAGNOSIS AND REPAIR

In case of failure or breakdown, please contact the Authorized Service Centre.

8. - EMC information according to IEC 60601-1-2

The information contained in this section (such as separation distances) is in general specifically written with regard to this model. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

GENERAL NOTES

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and need to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use of this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

ELECTROMAGNETIC EMISSIONS		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
EMISSIONS	**COMPLIANCE ACCORDING TO**	**ELECTROMAGNETIC ENVIRONMENT**
RF emissions (CISPR 11)	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
CISPR Emissions Classification	Class B	The equipment is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	

ELECTROMAGNETIC IMMUNITY			
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.			
IMMUNITY AGAINST	**IEC 60601-1-2 TEST LEVEL**	**COMPLIANCE LEVEL (of this device)**	**ELECTROMAGNETIC ENVIRONMENT**
electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: ± 6 kV air discharge: ± 8 kV	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.
electrical fast transients / bursts (IEC 61000-4-4)	power supply lines: ± 2 kV longer input / output lines: ± 1 kV	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
surges on AC mains lines (IEC 61000-4-5)	Common mode: ± 2 kV differential mode: ± 1 kV	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	Equipment which emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference.
voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95%, 0.5 periods dip 60%, 5 periods dip 30%, 25 periods dip >95%, 5 seconds	>95%, 0.5 per. 60%, 5 per. 30%, 25 per. >95%, 5 sec.	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions insure that batteries are installed and charged. Insure that battery life exceeds longest anticipated power outages or provide an additional uninterruptible power source.

This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended separation distance**
Conducted RF *RF coupled into lines* *(IEC 61000-4-6)*	*150 kHz to 80 MHz* *outside ISM bands*[a]	*3 Vrms*	d=1.2/V1]√P
radiated RF *(IEC 61000-4-3)*	*150 kHz to 80 MHz* *in ISM bands*[a]	*10 Vrms*	d=1.2/√P 80 MHz to 800MHz
	80 MHz – 2.5 GHz	*10 V/m*	d=2.3√P 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Recommended separation distances between portable and mobile RF communications equipment and the equipment

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTERS IN METERS		
	150 kHz – 80 MHz d=1.2/V1]√P	80 MHz to 800MHz d=1.2/V1]√P	800 MHz to 2.5 GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

DOCUMENTS IDENTIFICATION FOR INSTRUCTIONS
IDENTIFICATION NUMBER
ISSUING DATE
CONTENTS AND DATE OF REVISION